

## **REMARKS**

This is a full and timely response to the Final Office Action sent electronically by the U.S. Patent and Trademark Office on November 27, 2007. This paper is submitted with a request and the fee for a two-month extension of time. The response is believed timely in that the two-month date of April 27, 2008, fell on a Sunday. Claims 11, 12, 21-23, 26 and 39-41 remain pending in the present application. Claim 11 has been amended. The subject matter of amended claim 11 is illustrated in FIGs. 2C, 7A and 7B and presented in the related detailed description of Applicants' specification. Therefore, no new matter is introduced.

In view of the foregoing amendments and following remarks, reconsideration and allowance of the present application and claims are respectfully requested.

### **Response to Claim Rejections under 35 U.S.C. §112, first paragraph – Claims 11, 12, 21-23, 26 and 39-41**

#### **A. Statement of the Rejection**

Claims 11, 12, 21-23, 26 and 39-41 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. Specifically, the Office Action indicates that the amendment to claim 11, namely, the addition of “a terminal located on an external surface of the single use module for conductively receiving power from a source external to the single use module,” is allegedly new matter because the limitation is not taught by the specification as originally filed.

#### **B. Discussion of the Rejection**

Applicants respectfully disagree.

In accordance with the Manual of Patent Examining Procedure, Section 2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, “Written Description” Requirement [R-2], “It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification.” The guidelines clearly state, “[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations

using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Applicants’ originally submitted FIGs. 2C, 7A and 7B illustrate a terminal that extends from a single-use module, the terminal having conductors on an external surface of the single-use module. Paragraph [0047] clearly states through receptacle 722 and terminals 716, reusable module 720 can thus supply power to single-use module 710 and can receive a test result signal. Thus, Applicants have showed possession of the claimed invention and all of its limitations using such descriptive means as words and figures.

Although Applicants respectfully disagree, in an effort to advance prosecution of the application, Applicants have amended claim 11 such that the claim no longer recites the limitation of conductively receiving electrical power. Accordingly, Applicants request that the rejection of claims 11, 12, 21-23, 26 and 39-41 under 35 U.S.C. § 112, first paragraph be withdrawn.

## **Response to Claim Rejections under 35 U.S.C. §103 – Claims 11, 12, 21-23, 26 and 39-41**

### **A. Statement of the Rejection**

Claims 11, 12, 21-23, 26 and 39-41 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent Application Publication 20020004246 to Daniels et al. (hereinafter *Daniels*) in view of U.S. Patent No. 6,217,744 to Crosby (hereinafter *Crosby*) further in view of U.S. Patent No. 5,371,687 to Holmes II, et al. (hereinafter *Holmes*).

### **B. Discussion of the Rejection**

For a claim to be properly rejected under 35 U.S.C. § 103,

“[t]he PTO has the burden under section 103 to establish a *prima facie* case of obviousness. In order to make a proper *prima facie* case of obviousness; three basic criteria must be met, as set forth in MPEP § 706.02(j). First, there must be some suggestion or motivation; either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure."

Applicants' independent claim 11, as amended, includes at least one feature that is not disclosed, taught or suggested by the proposed combination of *Daniels*, *Crosby* and *Holmes*. Specifically, the proposed combination fails to disclose, teach or suggest at least "the terminal of the single use module configured to be inserted into a receptacle of a reusable module."

Concerning *Daniels*, the Office Action states

"*Daniels et al.* fail to teach the first and second photodetectors and medium contained in a single-use module that can be inserted into a reusable module and the single use module comprising an external terminal receiving electrical power for the light source, the first and second photodetectors and communicating signals between the reusable module and the single use module."

See Office Action, pg. 4, lines 7-12.

*Crosby* is cited for its alleged disclosure of a device that may alternatively be placed into the console for the transfer of data and to provide electrical power (column 7, lines 6-10). See Office Action page 5, lines 2-4.

Applicants respectfully disagree with this interpretation of *Crosby*. The cited portion of *Crosby* describes the embodiment of FIG. 4 and is as follows. "A visual indicator 22 shows the best place for location and an indentation in the console allows the disposable device to be placed and remain there, but in practice anywhere within a few centimeter range will work."

A console 24 with a visual indicator 22 and an indentation upon which a disposable analysis device 20 can be placed to remain at rest on the console does not disclose, teach or suggest a terminal of the single use module configured to be inserted into a receptacle of the reusable module. The verb "insert" means to put or introduce into the body of something. Thus, the disposable analysis device 20 placed

upon an indentation on the external surface of the console 24 does not disclose, teach or suggest a terminal that is inserted into a receptacle of the reusable module.

*Holmes* is cited for its alleged disclosure of a reusable module that has a terminal for insertion of a single-use module (housing mated to data processing module, column 3, lines 6-10) that has a terminal located on an external surface of the single-use module for conductively receiving electrical power from a source external to the single-use module.

Applicants respectfully disagree with this interpretation of *Holmes*. The cited portion of *Holmes* is describing a multiple-use glucose measuring instrument that takes multiple glucose measurements on multiple patients each day. (See *Holmes*, column 1, line 66 to column 2, line 2.) According to *Holmes*,

“An instrument according to the invention has the capability to: (1) interface with a printer for printing quality control reports, patient records and the like; (2) store larger numbers of patient glucose readings and related data than glucose measuring instruments typically are capable of storing; (3) perform various calculations on the data; (4) interface both to a number of different types of glucose measuring instruments and to a "notebook"-type computer which is capable of even greater data storage and calculation capability than the instrument of the invention itself; and, (5) provide a system lockout if quality control results of the unit are out of range.”

See *Holmes*, column 2, lines 17-30.

It is clear that the instrument disclosed by *Holmes* is a multiple-use glucose measuring instrument intended to store patient glucose readings on numbers of patients, perform various calculations on the data and to communicate the data via an interface with a printer and to a number of different types of glucose measuring instruments as well as to a notebook computer. Thus, *Holmes* does not disclose, teach or suggest a single-use module of any kind.

Thus, the proposed combination does not disclose, teach or suggest “the terminal of the single-use module configured to be inserted into a receptacle of a reusable module.” For at least this reason, the proposed combination fails to establish a *prima facie* case of obviousness with respect to Applicants’ claim 11. Accordingly,

favorable reconsideration and withdrawal of the rejection of independent claim 11 under 35 U.S.C. §103(a) are respectfully requested.

Furthermore, Applicants' independent claim 11, as amended, includes at least one additional feature that is not disclosed, taught or suggested by the proposed combination of *Daniels*, *Crosby* and *Holmes*. Specifically, the proposed combination fails to disclose, teach or suggest at least "the terminal comprising conductors along the external surface of the single-use module."

*Crosby* is further cited for its alleged disclosure of the possibility of directly connecting the device to a reader for power and for information gathering (column 6, lines 57-67). Office Action, pg. 5, lines 5-6.

However, when read in context it is clear that *Crosby* teaches away from such a direct electrical connection. Moreover, *Crosby* is entirely silent regarding the location and arrangement of an electrical connection and more specifically the location and arrangement of the conductors of such a connection. For ease of analysis the cited portion of *Crosby* follows.

"While it would be possible to directly electrically connect the device to a reader (i.e.: with an electrical connector), there are disadvantages of this approach including cost, potential contamination of the connector, need for precise placement in the connector, and power requirements for communication. The present invention uses a different system of communication based on telemetry."

See *Crosby*, column 6, lines 60-67.

It is clear that *Crosby* suggests not using a direct electrical connection for reasons of cost, potential contamination, as well as the need for precise alignment and power. Despite this clear and unambiguous statement against the use of a direct electrical connection, the Office Action concludes it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a terminal on an external surface of the single-use module for receiving electrical power from a source as taught by *Holmes*, to provide sample measurements over an extended period of time longer than the battery life of a device. Applicants note that the Supreme Court has held that "teaching away" from the claimed invention by the prior art is one important indicium of nonobviousness. *U.S. v. Adams*, 383 U.S. 39, 148

USPQ 479 (1966). The Federal circuit has also held that “teaching away” is strong evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed. Cir. 1986). Such teaching away should be weighed heavily in determining the nonobviousness of Applicants’ claims.

*Holmes* is cited for its alleged disclosure of a terminal located on an external surface of the single-use module for conductively receiving electrical power from a source external to the single use module (housing is mated to a data processing module and conductors connect the module to an external power supply column 3, lines 19-36). See Office Action, page 5, lines 13-17.

Applicants disagree for at least the reason that *Holmes* does not teach a single-use module. As shown above, *Holmes* is a multiple-use glucose measuring instrument intended to store patient glucose readings on numbers of patients, perform various calculations on the data and to communicate the data via an interface with a printer and to a number of different types of glucose measuring instruments as well as to a notebook computer. Thus, *Holmes* does not disclose, teach or suggest a single-use module of any kind.

Assuming *arguendo* that *Holmes*’ instrument is still considered to be a single-use module, Applicants further disagree for at least the reason that each meter or module illustrated in *Holmes* is arranged with a receptacle for receiving a corresponding electrical connector. For example, FIG. 2 and FIG. 3 reveal a connector socket 134 for coupling to a nine-pin connector 132 provided on printed circuit board 64. FIG. 3 reveals a meter 42 with respective receptacles for receiving adapter sockets 160 and 162. FIG. 5 shows a connector socket 234 for coupling to the nine-pin connector 132 (FIG. 2) and a meter 44 having a serial I/O port socket that receives plug 262. FIG. 7 shows a connector socket 334 for coupling to the nine-pin connector 132 (FIG. 2) and a meter 46. The meter 46 is connected electrically to the circuitry on printed wiring board 350 by a complimentary connector 354 and a socket 356. Socket 356 is provided on one end of an insulated multiple conductor cable 358 which is provided with a jack 362 to connect printed wiring board 350 to the meter’s serial I/O port. FIG. 9 shows a connector socket 434 for coupling to the nine-pin connector 132 (FIG. 2) and a meter 48. The meter 48 is connected electrically to the

circuitry on printed wiring board 450 by a complimentary connector 454 and a socket 456. Socket 456 is provided on one end of an insulated multiple conductor cable 458 provided with a socket 462 to provide a connection to the meter's serial I/O port.

Accordingly, the receptacles and socket type connectors disclosed by *Holmes* cannot be said to disclose, teach or suggest Applicants' claimed terminal on a single-use device, the terminal comprising conductors along the external surface of the single-use module for at least the reason that none of the conductors is along the external surface of the single-use module. Thus, the proposed combination does not disclose, teach or suggest Applicants' claimed rapid diagnostic test system. Consequently, favorable reconsideration and withdrawal of the rejection of independent claim 11 under 35 U.S.C. §103(a) are respectfully requested for at least this separate and distinct reason.

Because independent claim 11 is allowable, dependent claims 12, 21-23, 26 and 39-41, which depend directly or indirectly from allowable independent claim 11, are allowable. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1998). Accordingly, favorable reconsideration and withdrawal of the rejection of dependent claims 12, 21-23, 26 and 39-41 under 35 U.S.C. §103(a) are respectfully requested.

**CONCLUSION**

Applicants respectfully submit that pending claims 11, 12, 21-23, 26 and 39-41 are allowable and that the present application is in condition for allowance. Accordingly, a Notice of Allowance is respectfully solicited. Should the Examiner have any comments regarding the Applicants' response, Applicants request that the Examiner telephone Applicants' undersigned attorney.

Respectfully submitted,

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